



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

January 11, 2024

EA-21-055

Jason Tilly
VP and General Counsel
North America Operations
Curium US LLC
111 Westport Plaza Drive
Suite 800
St. Louis, MO 63146

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03000001/2019003(DRSS) –
CURIUM US LLC

Dear Jason Tilly:

On October 29-30, 2019, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your Maryland Heights, Missouri, facility with continued in-office review through December 21, 2023. Additionally, the NRC's Office of Investigations completed an investigation on April 7, 2021. The purpose of the inspection and the investigation was to review a molybdenum-99 (Mo-99) and technetium-99m (Tc-99m) contamination incident that occurred on August 19, 2019. Your staff initially informed our inspector of this Mo-99/Tc-99m contamination incident at the conclusion of our inspection to review your biennial emergency exercise on October 17, 2019.

The enclosed inspection report presents the results of the reactive inspection. This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel. The inspector discussed the preliminary inspection findings with members of your staff at the conclusion of the on-site portion of this reactive inspection. Ms. Deborah A. Piskura, of my staff, conducted a final exit meeting by videoconference with you and other members of your staff on December 21, 2023, to discuss the inspection findings.

Based on the results of this inspection, ten apparent violations of NRC requirements were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations are associated with the Mo-99/Tc-99m contamination incident that occurred on August 19, 2019, resulting in a significant radiation exposure to a former worker as well as widespread contamination of your Maryland Heights facility. The apparent violations involved the failure to:

- (1) report, within 24 hours of discovery, an event that involved loss of control of licensed material that caused the release of radioactive material, so that, had an individual been present for 24 hours in the area, the individual could have received an intake in excess of one occupational annual limit on intake, as required by Title 10 of the Code of Federal Regulations (CFR) 20.2202(b)(2);
- (2) notify the NRC within 24 hours after the discovery of an unplanned contamination event as required by 10 CFR 30.50(b)(1);
- (3) assess dose to determine compliance with occupational dose equivalent limits by taking suitable and timely measurements of concentrations of radioactive materials in air in the work area, quantities of radionuclides in the body, or quantities of radionuclides excreted from the body as required by 10 CFR 20.1204(a);
- (4) conduct an adequate survey to ensure compliance with limits on licensed material released into sanitary sewerage, as required by 10 CFR 20.1501 and 10 CFR 20.2003(a)(2);
- (5) furnish dose information to an individual as required by 10 CFR 19.13(b)(1);
- (6) maintain records of surveys as required by 10 CFR 20.2103(a);
- (7) provide information to the Commission that is complete and accurate in all material respects as required by 10 CFR 30.9;
- (8) maintain Curium's Corrective Action Program as required by License Condition 18;
- (9) comply with the terms and conditions of the Certificate of Compliance (CoC) No. 9320 as required by 10 CFR 71.17(c)(2); and
- (10) implement Curium's standard operating procedure (SOP) for performing personal contamination surveys as required by License Condition 21.

The NRC is not proposing additional apparent violations as a result of the inspection or investigation at this time.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) request a Predecisional Enforcement Conference (PEC); or (2) request Alternative Dispute Resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Rhex A. Edwards at 630-829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended request.** A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful and can be obtained at <https://www.nrc.gov/docs/ML0310/ML031060071.pdf>.

You may also request ADR with the NRC in an attempt to resolve these issues. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the “mediator”) works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC’s program can be obtained at <https://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC’s program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR, and please also contact Rhex Edwards at the telephone number or email address listed above.**

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC’s “Agency Rules of Practice and Procedure” in 10 CFR 2.390, a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC’s Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC’s website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Rhex Edwards, Chief, Materials Inspection Branch at 630-829-9722 if you have any questions regarding this inspection.

Sincerely,



Signed by Curtis, David
on 01/11/24

David Curtis, Director
Division of Radiological Safety and Security

Docket No. 030-00001
License No. 24-04206-01

Enclosure:
Inspection Report No. 03000001/2019003(DRSS)

cc (w/encl): State of Missouri

Letter to J. Tilly from D. Curtis dated January 11, 2024.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03000001/2019003(DRSS) –
CURIUM US LLC

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DATE	1/9/2024		1/10/2024		1/11/2024		1/11/2024	

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No.: 030-00001

License No.: 24-04206-01

Report No.: 03000001/2019003(DRSS)

EA NO.: EA-21-055

Licensee: Curium US LLC

Facility: 2703 Wagner Place
Maryland Heights, MO 63043

Inspection Dates: October 29-30, 2019, with continued in office
review through December 21, 2023

Exit Meeting Date: December 21, 2023

Inspector: Deborah A. Piskura, Senior Health Physicist
Materials Inspection Branch

Approved By: Rhex A. Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Curium US LLC NRC Inspection Report 03000001/2019003(DRSS)

This reactive inspection was conducted at the Curium US LLC (Curium or licensee), Maryland Heights, Missouri, manufacturing facility. The inspection included review of the licensee's investigation of an incident that occurred on August 19, 2019, involving widespread molybdenum-99 (Mo-99) and technetium-99m (Tc-99m) contamination at the licensee's site. Specifically, a medical isotope depleted uranium shielded (MIDUS) shipping cask was released from a hot cell with a highly contaminated component remaining inside. When a waste management technician (WMT) opened the cask for cleaning, the WMT and the immediate area became contaminated, which subsequently caused extensive site contamination, personnel contamination of the affected individual, and shoe contamination of approximately 50 individuals, including members of the public. The contamination event resulted from the failure of the licensee's Health Physics (HP) Office, hot cell production staff, and waste management staff to follow the requirements of the MIDUS Cask Certificate of Compliance (CoC) and established standard operating procedures (SOPs). These failures set up conditions which led to the site wide contamination event and a significant dose to an individual directly involved in the event.

The inspector identified several opportunities for improvement and the need for corrective actions. First, this event revealed weaknesses in the licensee's identification of and response to a significant contamination incident at its site. Second, the licensee did not ensure that the hazards associated with cleaning MIDUS shipping casks, containing curie (Ci) quantities of residual Mo-99/Tc-99m in an uncontained and unmonitored environment, were sufficiently mitigated. Specifically, the licensee did not identify a potential pressurized or aerosolized release of residual Mo-99/Tc-99m contamination while opening the cask as a potential hazard. Third, the licensee released a MIDUS cask from the hot cell with contaminated components remaining inside which deviated from the cask CoC Safety Analysis Report (SAR), and subsequently failed to follow SOPs when responding to the contamination incident. The licensee's failure to follow the CoC SAR was a direct cause of the event.

During this event, the WMT who opened the cask initially identified contamination on their hands and attempted to notify their supervisor by phone. The WMT exited the restricted area and proceeded to spread contamination as they walked through unrestricted areas of Buildings 100 and the parking lot. The licensee did not identify the contamination in its parking lot for over an hour. Consequently, approximately 50 individuals, including non-radiation workers and contractors who are considered members of the public, walked through the contamination, further spreading it to other buildings at the licensee's facility. Instead of conducting a prompt and thorough assessment of this contamination event, the licensee only documented a portion of this contamination incident through limited surveys of the personnel and the impacted areas, which challenged the NRC's ability to assess this event.

Ten apparent violations of NRC requirements were identified during this inspection involving the licensee's failures to:

- (1) report, within 24 hours of discovery, an event that involved loss of control of licensed material that caused the release of radioactive material, so that, had an individual been present for 24 hours in the area, the individual could have received an intake in excess of one occupational annual limit on intake, as required by Title 10 of the Code of Federal Regulations (CFR) 20.2202(b)(2);
- (2) notify the NRC within 24 hours after the discovery of an unplanned contamination event as required by 10 CFR 30.50(b)(1);
- (3) assess dose to determine compliance with occupational dose equivalent limits by taking suitable and timely measurements of concentrations of radioactive materials in air in the work area, quantities of radionuclides in the body, or quantities of radionuclides excreted from the body as required by 10 CFR 20.1204(a);
- (4) conduct an adequate survey to ensure compliance with limits on licensed material released into sanitary sewerage, as required by 10 CFR 20.1501 and 10 CFR 20.2003(a)(2);
- (5) furnish dose information to an individual as required by 10 CFR 19.13(b)(1);
- (6) maintain records of surveys as required by 10 CFR 20.2103(a);
- (7) provide information to the Commission that is complete and accurate in all material respects as required by 10 CFR 30.9;
- (8) maintain Curium's Corrective Action Program (CAP) as required by License Condition 18;
- (9) comply with the terms and conditions of the CoC No. 9320 as required by 10 CFR 71.17(c)(2); and
- (10) implement Curium's SOP for performing personal contamination surveys as required by License Condition 21.

REPORT DETAILS

This reactive inspection was conducted at the Curium US LLC (Curium or licensee), Maryland Heights, Missouri, manufacturing facility. The inspection included review of the licensee's investigation of an incident that occurred on August 19, 2019, involving widespread molybdenum-99 (Mo-99) and technetium-99m (Tc-99m) contamination at the licensee's site.

The licensee's manufacture and distribution of Mo-99/Tc-99m generators are licensed under NRC license No. 24-04206-01. The licensee received its raw molybdenum-99 (Mo-99) from Curium's plant in Petten, the Netherlands. This material was shipped in an NRC-approved Type B container referred to as a medical isotope depleted uranium shield (MIDUS) cask.

1. Event Overview

On August 17 and 18, 2019, the licensee loaded two MIDUS casks (Casks 22 and 26) into its Cell 10 (a hot cell) and failed to remove the secondary containment vessel (SCV), referred to as the "sleeve" in the licensee's November 22, 2019, investigation of incident report, from each cask. Subsequently, the hot cell group released these casks from Cell 10 on August 18, 2019, with the SCVs, which were contaminated with curie (Ci) quantities of Mo-99/Tc-99m, remaining inside the inner casks. When the waste management group received these casks, the tracking sheets indicated that there were SCVs inside each cask, but there was no indication that residual Mo-99/Tc-99m liquid was in the casks.

On August 19, 2019, at approximately 8:30 a.m., the waste management technician (WMT) picked up three MIDUS casks, including casks 22 and 26, from B600 and transported them by forklift to B500. The casks were to be taken to B500 for cleaning, decontamination, and preparation for return to Petten, the Netherlands. Interviews with the WMT confirmed that they conducted surveys of the casks, but the survey readings were not recorded on the accompanying forms for each cask.

At approximately 9:00 a.m., the WMT placed one of the casks on a washing station for cleaning. The WMT removed the lid and the depleted uranium (DU) plug. Once they removed the DU plug, their electronic dosimeter alarmed, and a nearby survey meter alarmed reading "off-scale." The survey meter was positioned on a workbench approximately six feet behind the technician. The WMT described to the inspector that the plug for this cask was difficult to remove, requiring a little extra force, and pressure within the cask may have caused residual Mo-99/Tc-99m to become airborne, contaminating the WMT and the surrounding area. After removing the plug, the WMT saw the SCV inside the cask body and removed it from the cask using long forceps. The WMT held the sleeve in the forceps, walked to the decay-in-storage room, key carded into the room, and placed the sleeve in a bucket for decay-in-storage. The WMT returned to the wash station to reinstall the DU plug and the cask lid believing that once they secured the DU plug within the cask and reinstalled the cask lid, the radiation levels would decrease to background. The WMT then approached a survey meter and, from a distance of approximately six feet, recognized the survey meter was "off-scale" and continuously alarming. The WMT believed their gloves (two pairs) must be heavily contaminated, so they put on a new pair of gloves. The WMT then re-surveyed their hands, but the survey meter again read "off-scale." The WMT did not recognize that the contamination could also be on their shoes, clothing, and other articles; therefore, they did not attempt to perform additional surveys.

The WMT subsequently asked a coworker, who was working in an adjoining room, to call their supervisor to inform them of this contamination; however, the phone call went unanswered. The WMT informed the coworker of their hand contamination, and that they were proceeding to the health physics (HP) office. When the WMT walked towards a sodium iodide detector stationed at the building exit, the meter also read "off-scale" and alarmed as they approached the survey station from approximately 15 feet. The WMT assumed the level of hand contamination exceeded the capabilities of the survey instruments and portal monitors located outside of B500; therefore, they bypassed these units as they exited the building. The WMT was unaware of any possible contamination on the building floor, and contamination was further spread as they walked. The shoes of the coworker who was working in the adjoining room also became contaminated during this incident.

The WMT exited B500 wearing gloves and walked approximately 400 steps from B500 through the licensee's parking lot (an unrestricted area) to B100, arriving there at approximately 9:23 a.m. After entering B100, the WMT searched for their immediate supervisor walking through the hallways, the employee break room, and office areas including the HP cubicle room, until they arrived at the HP laboratory.

Upon entering the HP lab, the WMT informed the Radiation Safety Officer (RSO) and an HP technician that they believed that their hands were contaminated. The RSO and the HP technician surveyed the WMT's hands. Although the level of contamination on the gloves was not recorded at the time the survey was performed, the licensee documented in subsequent reports contamination of approximately 320,000-350,000 counts per minute (cpm) on the WMT's left hand and 250,000 cpm on their right hand. This count rate was approximately 1,000 times above background. The RSO and the HP technician attempted to decontaminate the WMT's hands for approximately 30 minutes by repeated cleansing with soap and water followed by more aggressive washes with a diluted bleach solution and scrubbing with a brush. The decontamination efforts were halted due to skin irritation and reaction to the cleaning solutions. The WMT remained in the HP lab, wearing their contaminated clothing and other articles, for approximately 90 minutes before the HP staff identified the contamination on the WMT's shoes. The WMT's shoes were then removed and placed in a plastic bag. As the RSO and the HP technician continued to survey the WMT, they identified contamination on additional items of clothing. The WMT was instructed to remove the remaining contaminated items, place all items in a separate plastic bag, and shower. After showering, the WMT was decontaminated to a level that the RSO deemed acceptable to be released from the site. The WMT then exited the site for the day. According to the WMT, the portal monitor continued to alarm when they exited even after decontamination efforts.

In addition to the contaminated WMT, the HP staff identified contamination on the floor of the HP laboratory and office areas. Attempts to decontaminate the floor with wipes were unsuccessful, and the HP lab was closed for approximately 48 hours after the event.

At approximately 10:00 a.m. on August 19, the HP office received numerous calls from individuals at various survey stations stating that their shoes were contaminated, and they were unable to clear the plant's portal monitors located in B200, B600, and B700. At this time, the licensee recognized that the WMT had tracked contamination from B500 into the parking lot and into B100. Numerous individuals, including some considered members of the public, were unaware of the contamination event and proceeded to walk through the parking lot further spreading the contamination in the parking lot and to other buildings at the licensee's site. The RSO contacted the Vice President of Operations at approximately 10:20 a.m., leaving a voice mail message describing the contamination incident. At approximately 10:40 a.m., the RSO

issued an announcement to stop all foot traffic in the buildings and the parking lot. Employees were instructed to remain in their present locations until further notice.

The HP staff performed direct reading surveys of the pedestrian walkway and the parking lot, identifying approximately 400 contaminated areas (hot spots) where the WMT had walked from B500 to B100. According to the staff interviewed during the inspection and the licensee's investigation of incident report, these initial surveys identified contamination readings ranging from 1,000 cpm (near B100) to 57,000 cpm (at a curb approximately 30 feet from B500). However, the licensee did not maintain records of surveys of the parking lot.

Between approximately 1:00 and 3:00 p.m., the licensee's Environment, Health, and Safety (EHS) specialist performed direct reading surveys of the cask wash station (room 505) in B500, including the benchtop and the floors. These surveys identified contamination levels ranging from 2,000 cpm to 360,000 cpm. The surveys characterized the contamination at the time of the measurement (approximately 4-6 hours after the incident) and did not account for the original amount of contamination at the time the WMT was cleaning the cask. According to Curium staff that the inspector interviewed, before the EHS specialist conducted these surveys, the other individual who worked in the building was unaware of the event and walked through the cask cleaning area, further spreading Mo-99/Tc-99m contamination to other areas of B500.

The licensee did not perform surveys of the other areas within B500 where contamination was tracked, including the path the WMT walked from the cask washing station to the waste storage room, and the path they walked to exit the building. The original amount of contamination deposited along the path in the parking lot and subsequently tracked to other areas of the parking lot and buildings within the site is unknown. Additionally, the HP staff surveyed vehicles prior to release, but the licensee did not maintain records of its surveys of vehicles cleared to leave its site.

The licensee convened an emergent Radiation Safety Committee (RSC) meeting during the late morning of August 19, 2019, to develop a plan for managing the site during this incident. The RSC's decontamination plan for the parking lot included: (1) mopping the WMT's path between B500 and B100; (2) scrubbing the WMT's path in the parking lot with a floor scrubber machine; (3) following the scrubbing efforts with mopping and rinsing; and (4) performing confirmatory surveys for the remaining contamination after cleaning efforts. The licensee implemented this plan at approximately 1:00 p.m.

The licensee initially established a release criterion of 300 cpm for the hot spots in the parking lot; however, its efforts to decontaminate the asphalt could not reduce the Mo-99/Tc-99m to that level. After attempts to reduce the contamination to 300 cpm were unsuccessful, the licensee increased its release criterion to 5,000 cpm. When the licensee's revised release criterion was also unsuccessful for several areas in the parking lot, the licensee covered hot spots exceeding 5,000 cpm with asphalt sealant to fix the contamination in place until decay. Several members of the licensee staff, including the entire HP office, the maintenance department, and production staff, performed surveys of the parking lot, and participated in the decontamination efforts. The licensee did not document the parking lot surveys. At approximately 10:00 p.m., the licensee staff completed the decontamination efforts for the parking lot and pedestrian footpath.

Approximately 50 individuals, including licensee employees (both radiation workers and non-radiation workers) and contractors (who are considered members of the public), walked through the contamination in the parking lot or other areas in various buildings where contamination was subsequently tracked. The licensee collected the shoes of these individuals and held them for

decay-in-storage prior to returning the shoes to their owners. The licensee did not maintain records of the initial surveys performed on the shoes quantifying the amount of contamination on them, or records of the final surveys performed on the shoes prior to release to their owners to demonstrate that the level of contamination was indistinguishable from background. Furthermore, the licensee did not maintain records to demonstrate the contamination of these 50 individuals was limited to shoe contamination.

1.1 Inspection Scope

The inspection was conducted using the appropriate portions of the inspection procedures (IPs) in effect at the beginning of the inspection to evaluate the widespread Mo-99/Tc-99m contamination event, and elevated shallow dose equivalent (SDE) to an individual, that occurred at the Maryland Heights facility on August 19, 2019. Approved IPs with their attached revision histories are located on the public website at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>. The inspectors reviewed selected procedures and records, observed activities, interviewed personnel, and toured selected facilities to assess licensee performance and compliance with Commission rules and regulations, license conditions, site procedures, and standards. Listed below are the inspection procedures that were used during this inspection.

- IP 83501 - Significant Uncontrolled Radiation Exposures
- IP 84900 - Low-Level Radioactive Waste Storage
- IP 86740 - Inspection of Transportation Activities
- IP 87103 - Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
- IP 87125 - Materials Processor/Manufacturer Programs
- IP 88035 - Radioactive Waste Processing, Handling, Storage, and Transportation

The detailed inspection scope is listed below:

- The inspector reviewed the licensee's oversight and implementation of its radiation protection program. The review included HP staffing and annual program reviews.
- The inspector reviewed selected records related to the event including draft and final versions of the November 22, 2019, investigation of incident report (Investigation of Incident No. 19-0088) and the SOPs related to the tasks performed by the generator production line, the waste management group (including procedures for cleaning the MIDUS cask), and HP procedures (including responding to and performing personnel contamination surveys). Additionally, the inspector reviewed survey records, dosimetry badge records, and dose assessment records related to the event. Specifically, the inspector reviewed the dosimetry vendor's monitoring report for the WMT and the licensee's dose assessment for the WMT. The NRC conducted an independent estimate of the dose to the WMT's leg based on the information provided in the licensee's investigation of incident report,
- The inspector interviewed the RSO, health physicists, technicians, the EHS specialist, the WMT, and the former site vice president. The inspector interviewed the WMT almost six months after they became contaminated during the August 19, 2019, incident; at the time of the interview, the WMT was no longer employed by the licensee,
- The inspector toured selected areas impacted by the contamination event. The inspector toured B500 and the cask cleaning station and observed a demonstration of the cask cleaning process. The inspector toured the cask washing station and the decay-in-storage room, where the contaminated SCV was stored, and performed a walk down of the WMT's path from B500 to the HP office. Specifically, the inspector conducted a walk down to reenact the path taken by the WMT from the cask cleaning area, through the parking lot, to B100 and the HP office and laboratory

- The inspector reviewed the licensee's SOPs that implemented the CAP.
- The inspector reviewed past contamination and elevated radiation exposure incidents described in Inspection Report Nos. 03000001/2016001(DNMS) [ML16071A290] and 03000001/2017001(DNMS) [ML17181A319]¹ to determine whether the licensee evaluated these past incidents when developing corrective actions for the August 19, 2019, event. At the time of the on-site inspection that began on October 29, 2019, the licensee had not fully implemented corrective actions for the event that occurred on August 19, 2019,
- The inspector reviewed the circumstances of the Mo-99/Tc-99m contamination incident to determine the applicability of NRC event reporting requirements as specified in 10 CFR Parts 20 and 30; and
- The inspector reviewed other aspects of the licensee's program including: (1) security of byproduct materials; (2) surveys; (3) area posting and labeling of material; and (4) training.

1.2 Observations and Findings

As described in the event overview above, on August 19, 2019, the licensee had an unplanned Mo-99/Tc-99m contamination event in its waste management building (B500). The unplanned contamination event occurred during cask cleaning operations when the WMT opened a cask to remove an SCV from the cask body, causing a release of Mo-99/Tc-99m into the air.

On August 20, 2019, approximately 30 hours post-event, the licensee determined that the SCV, the source term for this contamination event, was contaminated with approximately 1.2 Ci of loose Mo-99/Tc-99m contamination. After the NRC's onsite inspection on October 29-30, 2019, the licensee revised its estimate of the source term to 2.5 Ci (1.25 Ci Mo-99 and 1.25 Ci Tc-99m in equilibrium).

The licensee's investigation of incident report estimated the total activity (Mo-99 and Tc-99m) to be approximately 1,030 microcuries (μCi) in all unrestricted areas and approximately 4,850 μCi in all restricted areas. The licensee relied on these estimates in determining that it was not required to report the incident to the NRC.

Reporting Requirements

The inspector found that the licensee did not report the contamination event within 24 hours of discovery as required by 10 CFR 20.2202(b)(2). Under 10 CFR 20.2202(b)(2), the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (ALI), is a reportable event. Title 10 CFR Part 20 has established ALIs to limit the occupational exposure to workers, and the lowest (most conservative) ALI for Mo-99 is 1,000 μCi .

The licensee did not measure the WMT's intake (e.g., by bioassay) after the August 19, 2019, event. Although the licensee calculated a source term of 1.2 Ci for the SCV 30 hours after the incident, the licensee did not use this source term value (or the subsequently revised value of 2.5 Ci) to estimate activity at the cask washing station for purposes of determining reportability. Both the original and updated source term values clearly indicate a reportable event based on an ALI of 1,000 μCi (.001 Ci).

¹ At the time of these two inspections, the licensee was Mallinckrodt Nuclear Medicine, LLC. In 2019 the licensee changed its name to Curium US LLC.

Instead, the licensee calculated the activity in the cask wash station area (the WMT’s immediate work area) based on a survey of the room using the following equation:²

$$\frac{cpm}{\epsilon \times detector\ area \times 2.22 \times 10^6 \frac{dpm}{\mu Ci}} \times affected\ surface\ area$$

where:

cpm = counts per minute (detector count rate)

ϵ = detector efficiency = 0.234 cpm/dpm (see p. 10 of the investigation of incident report)

detector area = 15 cm² (see Attachment H of the investigation of incident report)

Affected surface area = 1.1 x 10⁵ cm² (see Attachment H of the investigation of incident report)

2.22 x 10⁶ = conversion factor

The licensee’s activity calculation for the cask wash station area was based on the results of a survey conducted using a Ludlum 26-3 probe (see Attachment B of the investigation of incident report). In its calculation, the licensee used a count rate of 50,000 cpm, based on the average of all values measured in the survey (including both the floor and work surface in the cask wash station area), to obtain an activity of 706 μ Ci (see Attachment H of the investigation of incident report).

The average count rate for the floor of the cask wash station area was 90,000 cpm, including “multiple hot spots” and a maximum of 360,000 cpm immediately in front of the work surface (see p. 8 and Attachment B of the investigation of incident report). Using the average count rate of 90,000 for the floor surface area and the licensee’s other values, the inspector calculated an average activity as follows:

$$\frac{90,000cpm}{0.234 \times 15\ cm^2 \times 2.22 \times 10^6 \frac{dpm}{\mu Ci}} \times 1.1 \times 10^5\ cm^2 = 1,270\ \mu Ci$$

Using the 90,000 cpm value is appropriately conservative considering that the maximum recorded value was 360,000 cpm, suggesting that the actual activity could have been much higher. In addition, the survey values were obtained approximately five hours post event and were not decay corrected to the time of the event. Therefore, the actual activity would have been higher at the time of the release than what is calculated here.

² See Attachment H of the investigation of incident report. The first part of the equation gives concentration in units of μ Ci per cm²; multiplying by the affected surface area (in cm²) gives activity in μ Ci.

If the activity of radioactive material released was based on the licensee's original source term value of 1.2 Ci (1,200,000 μ Ci), the WMT could have inhaled an amount of radioactive material that exceeded the lowest ALI (1,000 μ Ci) if they had been present for 24 hours. Further, based on the NRC's calculations using the licensee's approach, 1,270 μ Ci of radioactive material was estimated to have been released in the immediate area where the WMT normally was stationed (the cask cleaning area). Therefore, the WMT could have also inhaled an amount of radioactive material that exceeded the lowest ALI (1,000 μ Ci) if they had been present for 24 hours using the licensee's approach.

The inspector additionally determined that this unplanned contamination event was reportable within 24 hours under 10 CFR 30.50(b)(1) because the licensee restricted access to contaminated areas for a period of more than 24 hours; the contamination event involved a quantity of material greater than five times the lowest ALI in 10 CFR Part 20 Appendix B for the material; and the licensee restricted access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

First, the licensee informed the inspector that the contaminated areas were not decontaminated until several days later. The HP lab and offices, as well as Room 502 within B500, were restricted for several days. Additionally, according to interviews with several individuals, the licensee placed absorbent paper in several areas in B500 to cover the loose contamination from the Mo-99/Tc-99m incident. The absorbent paper remained in place until just prior to October 17, 2019, when the licensee removed the paper during an unrelated NRC inspection of the licensee's biennial emergency response exercise.

Second, the licensee determined that the activity level of the source term (the SCV) was 1.25 Ci of Mo-99 and 1.25 Ci of Tc-99m (or 1250 millicuries (mCi) for each). This value (1,250 mCi) is greater than five times the lowest (more conservative) ALI for Mo-99 as specified in 10 CFR Part 20 Appendix B, which is 1,000 μ Ci, or 1 mCi.

Third, the licensee restricted access to certain areas, such as the HP lab in B100, in order to decontaminate those areas from Mo-99, a radioisotope with a half-life greater than 24 hours (the half-life of Mo-99 is approximately 65.9 hours).

The inspector discussed the estimated Mo-99/Tc-99m contamination and the reporting criteria in 10 CFR 30.50(b) for this event during a teleconference on November 8, 2019. The inspector explained that the licensee did not include the 1.2 Ci (original estimate) source term (the SCV, which was the source of the contamination for this incident). Additionally, using the licensee's approach and values from the licensee's investigation of incident report, the NRC's estimates of the contamination were higher than the licensee's estimates. The inspector also pointed out that the RSO's assessment did not account for other areas and articles that were contaminated or likely to be contaminated that should have been included in the total.

After the November 8, 2019, teleconference, the licensee used the equation above to recalculate the activity in unrestricted areas (1,030 μCi) and restricted areas (4,850 μCi). The licensee added estimated levels of contamination for selected unrestricted and restricted areas of the facility to obtain these values (see Attachments G and H of the investigation of incident report). Because neither value (i.e., for unrestricted or restricted areas) was above 5,000 μCi , the licensee concluded that the 24-hour reporting requirement in 10 CFR 30.50(b)(1) was not triggered. However, based on the licensee's calculations, the total activity in all areas (both restricted and unrestricted) was 5,880 μCi ; thus, the total quantity of material exceeded five times the lowest ALI on intake for Mo-99 (1,000 μCi).

When an unplanned release of radioactive material occurs, the licensee must evaluate the conditions as soon as possible after the event to ensure compliance with reporting requirements. In this case, Curium did not conduct its assessment of the source term (the SCV) until approximately 30 hours after the event. If the NRC had been notified of this contamination incident in a timely manner, as required under the regulations, an inspector would have been sent to the site to conduct confirmatory measurements to assess the extent of contamination that had spread onsite. The licensee's failure to provide a 24-hour report prevented the NRC from evaluating the event while the facts and circumstances were current, and, in particular, prevented the NRC from interviewing and reenacting the event with the WMT before the WMT's employment was terminated. In addition, the NRC was unable to assess the licensee's identification, characterization, and documentation of the contamination event. Finally, because the licensee failed to make a timely notification, the NRC was unable to determine whether an overexposure or intake had occurred.

Additional Regulatory and License Condition Requirements

Title 10 CFR 20.1204(a) requires that, for purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under § 20.1502, take suitable and timely measurements of concentrations of radioactive materials in the air in work areas, quantities of radionuclides in the body, quantities of radionuclides excreted from the body, or combinations of these measurements. In this situation, the licensee was required to evaluate the WMT's occupational intake under 10 CFR 20.1502(b)(1), because, given the extent of the contamination event and the technician receiving skin contamination, the technician was an adult likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI.

The inspector determined that following the release, the licensee failed to take any of the measurements required in 10 CFR 20.1204(a). The licensee did not take timely and suitable measurements of concentrations of Mo-99/Tc-99m in the air at the cask washing station during and following the contamination event. Additionally, the inspector determined that the licensee failed to take timely and suitable measurements of quantities of radionuclides in the WMT's body, or excreted from their body, to characterize the radiological intake following the WMT's skin contamination. According to Curium's SOP-291-052, "Urine Screening Program" (effective date March 12, 2019), which is used to measure radioactive material in or excreted from a worker's body, urine samples are to be "collected immediately upon confirmation of radiological contamination in the skin, but no[t] to exceed six (6) hours following the contamination event." The licensee did not collect these samples. Because the licensee did not take any of the measurements specified in 10 CFR 20.1204(a), it failed to take timely and suitable

measurements of the occupational intake of Mo-99/Tc-99m for the WMT, an individual who was likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI.

The inspector also identified that the licensee failed to conduct adequate surveys as required by 10 CFR 20.1501 to ensure compliance with the limits in 10 CFR 20.2003(a)(2) for disposal of radioactive material by release into a sanitary sewer system. During follow-up inspections, the NRC inspector asked the licensee where the decontamination efforts for the WMT's hands occurred. The licensee informed the inspector that the individual's hands were decontaminated in a sink in the HP instrument room and showed the sink to the inspector. The inspector noted a blue sign posted above the sink indicating that it was not intended for sewer disposal of radioactive material. Without performing a survey of the quantity of radioactive material disposed into the sanitary sewerage system when performing decontamination measures on an individual's hands in a sink that was specifically posted as a "non-radioactive" sink, the licensee was unable to ensure that the concentration did not exceed the limits in 10 CFR Part 20 Appendix B.

The inspector additionally identified that the licensee failed to provide an annual report of occupational dose to an individual who received an occupational dose exceeding 1 mSv (100 mrem) to any individual organ or tissue for the 2019 monitoring period, as required by 10 CFR 19.13(b)(1). Specifically, the licensee performed a dose assessment and determined the WMT received a dose exceeding 100 mrem from the August 19, 2019, contamination event. However, during an interview with the inspector, the WMT stated that they had not received any information pertaining to their occupational dose exposure for the monitoring year that included August 19, 2019. The licensee entered the WMT's estimated dose from the August 19, 2019, event on a "Report of Personnel Contamination" form originally dated August 28, 2019. However, it appears that the WMT did not see this form, because the signature line for the "Contaminated Person" (the WMT) to sign the form was blank. Additionally, check boxes on the completed form indicating that the "original was placed in the individual's permanent record" and the "individual's permanent dose record was updated" were not checked on the completed form.

The inspector also reviewed the licensee's survey records associated with the August 19, 2019, contamination event. The inspector determined that the licensee did not maintain records of surveys that were performed on August 19, 2019, for Mo-99/Tc-99m contamination identified in the parking lot and in Buildings 100, 200, 500, 600, and 700 (see pages 8-9 of the licensee's investigation of incident report). Because surveys of these areas were required under 10 CFR 20.1501, the licensee's failure to maintain records of those surveys appears to be a violation of 10 CFR 20.2103(a). Additionally, the licensee did not maintain records of the surveys performed on the shoes confiscated from approximately 50 individuals who walked through contamination in the parking lot. Specifically, the licensee failed to quantify the amount of contamination on the shoes and did not record surveys of the shoes to demonstrate that the level of contamination was indistinguishable from background prior to returning the shoes to their owners. These failures by the licensee to maintain records of surveys prevented the NRC from assessing the amount of Mo-99/Tc-99m contamination involved in this incident and inhibited the NRC's ability to evaluate whether the licensee adequately identified, characterized, and remediated the contamination at its site.

Finally, while evaluating the event and associated documentation concerning the contamination spread at the facility, the inspector identified incomplete and inaccurate information that was submitted to the NRC, contrary to the requirements of 10 CFR 30.9. The inspector determined that the WMT's occupational dose history, which was submitted to the NRC by the licensee on NRC Form 4, was inaccurate. Specifically, for the monitoring period from January 1, 2019, to October 31, 2019, the WMT's NRC Form 4 indicates a dose of 0.357 rem SDE for the skin of the extremity receiving the maximum dose. The licensee's estimate of actual dose from the August 19, 2019, incident, which was 29.4 rem SDE to a localized area of the skin on the left lower leg (as documented on page 3 of the licensee's investigation of incident report), was not included on NRC Form 4 for the WMT that the licensee submitted to the NRC's Radiation Exposure Information and Reporting System (REIRS). Therefore, the reported dose information for the WMT during the January 1, 2019, to October 31, 2019, monitoring period was inaccurate. This information is material because the NRC relies on licensees to accurately report individual dose data into REIRS in order to make inspection and enforcement decisions.

The inspector reviewed Condition 18 of License No. 24-04206-01 and identified failures by the licensee to maintain a CAP to identify and correct deficiencies associated with radiation safety. The inspector identified the following examples where the licensee failed to promptly identify and correct significant conditions adverse to radiation safety:

1. Failing to identify that casks leaving the hot cell may contain SCVs. The licensee did not develop corrective actions for addressing SCVs that are left in the cask after being released from the hot cell, which contributed to the contamination incident.
2. Failing to identify and correct inadequate maintenance of survey records contrary to 10 CFR 20.2103(a). The licensee stated several times in its investigation of incident report that the HP staff failed to document its surveys. However, the licensee did not indicate if it initiated a separate CAP investigation for this failure to maintain survey records, identify the cause(s), or develop corrective actions for this failure to maintain survey records. This failure to maintain records of surveys was a condition adverse to radiation safety, and the licensee failed to implement corrective action to preclude repetition.

The inspector determined that the licensee's investigation of incident report No. 19-88 omitted key facts about the event that were pertinent to the understanding and conclusions of the licensee's investigation. For example, there was no mention of the 50 pairs of contaminated shoes. Additionally, the licensee's investigation developed no corrective actions for retrieving SCVs, which the licensee had attributed as a cause for the Mo-99/Tc-99m contamination incident. The licensee's investigation of incident report also provided no discussion of the previous corrective actions taken in response to a similar event (use of retrieval tool/reverse action tongs) that occurred in 2015 (Inspection Report No. 03000001/2016001, ML16071A290) or why those previous corrective actions were apparently ineffective. Finally, the licensee's investigation of incident report provided no investigation or corrective actions for this event in comparison to three previous contamination events in 2018 involving the same task (cask cleaning) and the same individual.

Curium received its bulk Mo-99 from its sister plant in Petten, the Netherlands, within an NRC approved MIDUS Type B shipping cask. Curium was a registered user of the MIDUS cask. Title 10 CFR 71.17(a) authorized Curium under a general license to transport licensed material in the MIDUS cask for which CoC No. 9320 had been issued by the NRC. As a registered user, the licensee was required by 10 CFR 71.17(c)(2) to comply with the terms and conditions of the CoC No. 9320. Condition 6.A., of CoC No. 9320, states, in part, that the package shall be

prepared for shipment and operated in accordance with the Package Operations in Chapter 7 of the CoC application. Enclosure 1 of the CoC application, dated January 30, 2017, contains the SAR. Section 7 of the SAR described the operations used to load the package for transport, unload the package, and prepare the empty package for transport. Additionally, Section 7 states, in part, that “the package shall be operated in accordance with the detailed written procedures that are based on, and consistent with, the operations described in this section.” Section 7.2.2, Item 5, states, in part, “lift the shield plug (and payload, if applicable) from the cask body. If the payload internals are not mechanically attached to the bottom of the shield plug or if they do not lift out with the shield plug, then remove them from the cask cavity.”

The inspector determined that on August 18, 2019, Curium failed to comply with the terms and conditions of CoC No. 9320 as required by 10 CFR 71.17(c)(2). Specifically, when performing unloading operations on casks Nos. 22 and 26, Curium failed to remove the SCV, part of the payload internals, from those casks. The casks containing the SCVs were then transferred out of the hot cell to the waste management building. On August 19, 2019, the WMT opened cask No. 26 for cleaning, releasing residual contamination from the SCV and leading to a significant contamination event. This contamination event resulted in a significant dose to a localized area of the skin on the WMT’s left lower leg.

Lastly, Condition 21 of License Number 24-04206-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter dated November 15, 2013. Item 3 of the letter dated November 15, 2013, states in part that the licensee will develop, implement, and maintain procedures associated with areas including Operating Procedures (Bullet 6). The inspector identified one failure by the licensee to implement SOPs that are required by this license condition. Specifically, the inspector determined that the licensee failed to follow SOP-33-141 “Personal Contamination Survey,” effective date April 25, 2019. SOP-33-141, Section I, Primary Personal Contamination Survey, Item D.4., which requires, in part, that if contamination is identified, to remain in the area to prevent the spread of contamination from spreading to other areas.

On August 19, 2019, the WMT identified that they had become contaminated by Mo-99/Tc-99m but did not remain in the area to prevent the spread of contamination to other areas as required by the SOP. Specifically, the WMT exited their workspace in B500 and walked through the licensee’s parking lot to B100, spreading Mo-99/Tc-99m contamination in the licensee’s parking lot and several areas within the two buildings.

Summary of Apparent Violations

Based on the inspection, ten apparent violations of NRC requirements were identified:

1. Title 10 CFR 20.2202(b)(2) requires, in part, that each licensee, within 24 hours of discovery of the event, report any event involving the loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours the individual could have received an intake in excess of one occupational annual limit on intake. Table 1, “Occupational Values,” of Part 20 Appendix B, states that the annual limit on intake for Mo-99 (Class Y) is 1,000 μCi .

Contrary to the above, the licensee failed to report, within 24 hours of an event that occurred on August 19, 2019, the release of radioactive material inside a restricted area, so that, had an individual been present for 24 hours, an individual could have received an intake in excess of one occupational annual limit on intake. Specifically, based on the licensee's survey data obtained approximately 5 hours after the event, the NRC estimated that 1,270 μCi of Mo-99/Tc-99m were released in the immediate vicinity of a worker from an internal component of a shipping cask that was contaminated with at least 2.5 Ci (2,500,000 μCi) of Mo-99/Tc-99m. This release contaminated the worker, who was cleaning the cask in the licensee's waste management building. Based on the estimated activity, had the worker been present for 24 hours, they could have received an intake in excess of 1,000 μCi , the occupational annual limit on intake for Mo-99.

2. Title 10 CFR 30.50(b)(1), requires, in part, that each licensee notify the NRC within 24 hours after the discovery of an unplanned contamination event that: (i) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; (ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and (iii) has access to the area restricted for a reason other than to allow isotopes with a half-life less than 24 hours to decay prior to decontamination.

Contrary to the above, the licensee failed to notify the NRC within 24 hours after the discovery of an unplanned contamination event on August 19, 2019, that required access to contaminated areas to be restricted for more than 24 hours by imposing additional radiological controls or prohibiting entry into the area, involved a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20, and had access restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination. Specifically, after the unplanned contamination event on August 19, 2019, the licensee prohibited entry into Rooms 505 and 502 within Building 500, as well as the health physics lab and offices within Building 100, for over 24 hours and required additional radiological controls (absorbent paper, additional protective clothing, additional signage, and locks). In addition, the contamination involved an internal component of a shipping cask contaminated with approximately 1.25 Ci (1,250,000 μCi) of Mo-99 and 1.25 Ci (1,250,000 μCi) of Tc-99m, greater than five times the 10 CFR Part 20 Appendix B amounts of 1,000 μCi and 80,000 μCi , respectively. Finally, access to the areas was restricted to allow for decontamination from Mo-99, which has a half-life greater than 24 hours (65.9 hours).

3. Title 10 CFR 20.1204(a) states that, for the purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under 20.1502, take suitable and timely measurements of concentrations of radioactive material in air in work areas, quantities of radionuclides in the body, quantities of radionuclides excreted from the body, or combinations of these measurements.

10 CFR 20.1502(b)(1) states that each licensee shall monitor the occupational intake of radioactive material by and assess the committed effective equivalent to adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limits of intake in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20.

Contrary to the above, on August 19, 2019, the licensee failed to assess dose used to determine compliance with occupational dose equivalent limits as required under 10 CFR 20.1502 by taking suitable and timely measurements of concentrations of radioactive material in air in work areas, quantities of radionuclides in the body, quantities of radionuclides excreted from the body, or combination of these measurements. Specifically, after a worker was exposed to a release of airborne radioactivity that made them likely to receive, in one year, an intake in excess of 10 percent of the applicable annual limit of intake in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20, the licensee failed to conduct air sampling in the affected work area in order to take suitable and timely measurements of concentrations of radioactive material in air in work areas. The licensee also failed to take measurements of quantities of radionuclides in the individual's body or excreted from the individual's body.

4. Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of residual radioactivity, and the potential radiological hazards of the radiation levels and residual radioactivity detected.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

10 CFR 20.2003(a)(2), states in part, that a licensee may discharge licensed material into sanitary sewerage if the quantity of licensed material that the licensee releases in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of Appendix B to Part 20. The concentration of Mo-99 listed in table 3 of appendix B is 2E-4 microcuries per milliliter.

Contrary to the above, on August 19, 2019, the licensee did not perform surveys to assure compliance with 10 CFR 20.2003(a)(2), which limits the quantity of licensed material disposed by release into a sanitary sewerage system. Specifically, the licensee performed personnel decontamination measures on an individual's hands in a sink that was specifically posted as a "non-radioactive" sink, without performing a survey of the quantity of radioactive material disposed of into the sink, and thus into the sanitary sewerage system, to ensure that the concentration did not exceed the limits in 10 CFR Part 20 Appendix B.

5. Title 10 CFR 19.13(a) states, in part, that radiation exposure data for an individual and the result of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section.

10 CFR 19.13(b)(1) states, in part, that the licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue.

10 CFR 20.1502(b)(1) states that each licensee shall monitor the occupational intake of radioactive material by and assess the committed effective equivalent to adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limits of intake in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20.

Contrary to the above, the licensee failed to provide an annual report of occupational dose to an individual monitored under 10 CFR 20.1502 who received an occupational dose exceeding 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue for the 2019 monitoring year. Specifically, the licensee performed a dose assessment and determined that the individual received a dose exceeding 100 mrem from an August 19, 2019, contamination event. However, as of February 19, 2020, the individual had not received any information regarding their occupational dose exposure for the monitoring year that included August 19, 2019.

6. Title 10 CFR 20.2103(a) requires, in part, that each licensee shall maintain records showing the results of surveys and calibrations required by 10 CFR 20.1501, and that the licensee shall retain these records for three years after the record is made.

10 CFR 20.1501(a) requires, in part, that each licensee shall make or cause to be made, surveys of areas, including the subsurface, that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of residual radioactivity, and the potential radiological hazards of the radiation levels and residual radioactivity detected.

Contrary to the above, as of October 29, 2019, the licensee did not maintain records of the results of surveys as required by 10 CFR 20.1501. Specifically, the licensee failed to document the results of surveys performed on August 19, 2019, in the parking lot, Building 100, Building 200, Building 600, and Building 700, after those areas became contaminated during a contamination incident involving a source term with estimated activity of 2.5 Ci of Mo-99/Tc-99m.

7. Title 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, on April 30, 2020, the licensee failed to provide information to the Commission that was complete and accurate in all material respects. Specifically, the licensee provided dose information on NRC Form 4 for the January 1, 2019, to October 31, 2019, monitoring period for an individual who became contaminated in an event on August 19, 2019, and submitted that form to the NRC through the Radiation Exposure Information and Reporting System (REIRS). The licensee reported 0.357 rem SDE for the individual on NRC Form 4; however, according to the licensee's inspection of incident report, the licensee calculated a SDE of 29.4 rem to a localized area of the skin on the left lower leg for this individual as a result of the August 19, 2019, event. This information is material because the NRC relies on licensees to accurately report individual dose data into REIRS in order to make inspection and enforcement decisions.

8. Condition 18 of License No. 24-04206-01, Amendment 99, requires, in part, that the licensee maintain a corrective action program (CAP) to identify and correct deficiencies associated with radiation safety, and that, in the case of significant conditions adverse to radiation safety, the CAP measures shall assure that the cause of the condition is determined, and corrective action taken to preclude repetition.

Contrary to the above, the licensee did not identify the cause of a significant condition adverse to radiation safety and corrective actions to preclude repetition for the incident on August 19, 2019. Specifically, the licensee failed to identify that the SCV remaining in the cask after leaving the hot cell was a cause of the Mo-99/Tc-99m contamination incident and did not identify corrective actions to preclude repetition. In addition, the licensee identified several instances of failures to maintain records of surveys (including surveys of outdoor walking areas, several buildings, and affected individuals), but did not identify corrective actions to preclude repetition.

9. Title 10 CFR 71.3 states, in part, that except as authorized in a general license or specific license issued by the Commission, no licensee may deliver licensed material to a carrier for transport or transport licensed material.

10 CFR 71.17(a) states, in part, that a general license is issued to any licensee of the Commission to transport licensed material in a package for which a license, certificate of compliance (CoC) or other approval has been issued by the NRC.

10 CFR 71.17(c)(2) states, in part, that each licensee issued a general license under paragraph 10 CFR 71.17 (a) shall comply with the terms and conditions of the license, CoC or other approval, as applicable.

NRC CoC No. 9320, applies to the MIDUS package for the transport of medical isotopes. Condition 6.A. of CoC No. 9320 states, in part, that the package shall be prepared for shipment and operated in accordance with the Package Operations in Chapter 7 of the CoC application.

Chapter 7, "Package Operations," of Safety Analysis Report, Rev. 6 (Enclosure 1 of the CoC application), dated January 30, 2017, Section 7.2, "Package Unloading," describes package unloading operations. Subsection 7.2.2, "Removal of Contents," step 3, requires, in part, that the cask be transferred to the hot cell. Step 5 states, in part, "If the payload internals are not mechanically attached to the bottom of the shield plug or if they do not lift out with the shield plug, then remove them from the cask cavity."

Contrary to the above, on August 18, 2019, Curium, a general licensee under 10 CFR 71.17(a), failed to comply with the terms and conditions of CoC No. 9320 as required by 10 CFR 71.17(c)(2). Specifically, when performing unloading operations in the hot cell on cask Nos. 22 and 26, Curium, failed to remove the SCV, part of the payload internals, from those casks. The casks containing the SCVs were then transferred out of the hot cell to the waste management building. Subsequently, on August 19, 2019, a waste management technician opened cask No. 26 for cleaning, releasing residual contamination from the SCV and leading to a significant contamination event.

10. Condition 21 of License Number 24-04206-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in a letter dated November 15, 2013.

Item 3 of the letter dated November 15, 2013, states, in part, that the licensee commits to developing, implementing, and maintaining procedures including Operating Procedures (Bullet 6).

Licensee operating procedure, SOP 33-141, "Personal Contamination Survey," effective April 25, 2019, Section I, "Primary Personal Contamination Survey," Item D.4. requires, in part, that if contamination is identified, to remain in the area to prevent the spread of contamination from spreading to other areas.

Contrary to the above, on August 19, 2019, a Curium worker became contaminated with Mo-99/Tc-99m after handling a component of a MIDUS shipping cask contaminated with curie quantities of residual Mo-99/Tc-99m and did not remain in the area to prevent the spread of contamination from spreading to other areas. Instead, the individual exited their workspace in Building 500, and walked through the licensee's parking lot to Building 100, spreading Mo-99/Tc-99m contamination in the parking lot and several areas within the two buildings.

1.3 Conclusions

The inspector reviewed various documents, interviewed individuals, and gathered data associated with the contamination event that occurred at the facility on August 19, 2019. The inspector used this information in association with applicable inspection procedures and identified 10 apparent violations of NRC requirements. Ten apparent violations of NRC requirements were identified during this inspection involving the licensee's failures to:

- (1) report, within 24 hours of discovery, an event that involved loss of control of licensed material that caused the release of radioactive material, so that, had an individual been present for 24 hours in the area, the individual could have received an intake in excess of one occupational annual limit on intake, as required by 10 CFR 20.2202(b)(2);
- (2) notify the NRC within 24 hours after the discovery of an unplanned contamination event as required by 10 CFR 30.50(b)(1);
- (3) assess dose to determine compliance with occupational dose equivalent limits by taking suitable and timely measurements of concentrations of radioactive materials in air in the work area, quantities of radionuclides in the body, or quantities of radionuclides excreted from the body as required by 10 CFR 20.1204(a);
- (4) conduct an adequate survey to ensure compliance with limits on licensed material released into sanitary sewerage, as required by 10 CFR 20.1501 and 10 CFR 20.2003(a)(2);
- (5) furnish dose information to an individual as required by 10 CFR 19.13(b)(1);
- (6) maintain records of surveys as required by 10 CFR 20.2103(a);
- (7) provide information to the Commission that is complete and accurate in all material respects as required by 10 CFR 30.9;
- (8) maintain Curium's CAP as required by License Condition 18;
- (9) comply with the terms and conditions of the CoC No. 9320 as required by 10 CFR 71.17(c)(2); and
- (10) implement Curium's SOPs for performing personal contamination surveys as required by License Condition 21.

2. Exit Meeting Summary

The NRC inspector presented the preliminary inspection findings following the onsite inspection on October 30, 2019, and during the videoconference exit meeting on December 21, 2023. The licensee acknowledged the findings presented.

LIST OF INDIVIDUALS CONTACTED

- Lee Crockett, Waste Management Technician (former employee)
 - # Manuel Diaz, Radiation Safety Officer/Health Physics Manager
 - Ronald J. Dobey, Jr., CHP, Consultant
 - # Elizabeth Engelmann, Senior Health Physicist (former employee)
 - #+ Anthony R. Kinney, Vice President, Legal
 - # Corey Lamb, EHS Specialist
 - Nhi (Lily) Ma, Health Physics Technician (former employee)
 - # Richard C. Proehl, Vice President, Operations-North America (former employee)
 - James R. Schuh, Health Physicist (Contractor)
 - + Dan Szatkowski, Radiation Safety Officer
 - + Jason Tilly, Vice President & General Counsel
 - + Amy Roma (External Counsel), Hogan Lovells
 - + Jim McGovern (External Counsel), Vinson & Elkins LLP
 - + Samuel Rackear (External Counsel), Vinson & Elkins LLP
 - Individual A, Waste Management Technician (former employee)
 - EnergySolutions, LLC
 - Aleksandr Gelfond, P.E., Cask Division Engineering/Licensing Manager
- # Attended on site meeting on October 30, 2019.
- + Attended final videoconference exit meeting on December 21, 2023.
- * To protect their personal privacy, the identity of the individual who became contaminated and for whom radiation exposure information has been discussed has not been included in this report.

INSPECTION PROCEDURES USED

- IP 83501 - Significant Uncontrolled Radiation Exposures
- IP 84900 - Low-Level Radioactive Waste Storage
- IP 86740 - Inspection of Transportation Activities
- IP 87103 - Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
- IP 87125 - Materials Processor/Manufacturer Programs
- IP 88035 - Radioactive Waste Processing, Handling, Storage, and Transportation

LIST OF ACONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALI	Annual Limit on Intake
CAP	Corrective Action Program
Ci	Curie
CoC	Certificate of Compliance
CFR	Code of Federal Regulations
cpm	counts per minute
DU	depleted uranium
dpm	disintegrations per minute
EHS	Environment, Health, and Safety
HP	health physics
ICR	Institute of Conflict Resolution
IP	inspection procedure
mCi	millicurie
MIDUS	medical isotope depleted uranium shielded transport package
Mo-99	molybdenum-99
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
REIRS	Radiation Exposure Information and Reporting System
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SAR	Safety Analysis Report
SCV	secondary containment vessels
SDE	Shallow Dose Equivalent
SOP	Standard Operating Procedure
Tc-99m	technetium-99m
TEDE	Total Effective Dose Equivalent
WMT	Waste Management Technician
μCi	microcuries